K022482

AUG 1 3 2002

GE Medical Systems
Information Technologies

General Electric Company
4502 Woodland Corporate Blvd., Tampa, FL 33614
813 887-2000

SUMMARY OF SAFETY AND EFFECTIVENESS

June 24, 2002

Sensa-Cuff

A. Submitter

GE Medical Systems Information Technologies
4502 Woodland Corporate Boulevard
Tampa, FL 33614

B. Company Contact

Primary:
Melissa Robinson, Regulatory Affairs Specialist
Phone: 813-887-2133
Fax: 813-887-2552

Secondary:
Tom English, Global QA/RA
Phone: 813-887-2107
Fax: 813-887-2413

C. Device Name

Trade Name:	Sensa-Cuff
Common Name:	Blood Pressure Cuff
Classification/Product Code:	DXQ-870.1120

D. Predicate/Legally Marketed Devices

DURA-CUF®-Preamendment
Critikon Company, LLC

E. Device Description

The device comprises tubing attached to an inelastic sleeve with an integrated inflatable bladder that is wrapped around the patient's limb and secured by hook and loop closure. The device tubing is connected to a non-invasive blood pressure measurement system.

F. Intended Use

The Sensa-Cuff Blood Pressure Cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available in pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.

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G. Testing

The Sensa-Cuff Blood Pressure Cuffs were tested according to the applicable sections of the following standards:

- SP-9 Nonautomated Sphygmomanometer
- BS EN 1060 Non-Invasive Sphygmomanometers
- ISO 10993 Biological Evaluation of Medical Devices

H. Comparison to the Predicate Device

COMPARISON OF THE Critikon Sensa-Cuff to the Critikon DURA-CUF®		
Features	**DURA-CUF®**	**Sensa-CUFF**
Intended Use	Indirect measurement of blood pressure	Indirect measurement of blood pressure
Patient Populations	Adults/pediatrics	Adults/pediatrics
Material	Cuff Substrate: Polyurethane coated nylon woven cloth Tubing: SE-BS Thermoplastic elastomer Hook: Molded Nylon Loop: Nylon	Cuff material: Woven nylon Film (bladder): Ethylene vinyl acetate copolymer (EVA) Tubing: PVC Ribbon: Textured polyester Hook: Molded Nylon Loop: nylon
Tube Configuration	1 and 2 tube	1 and 2 tube
Sizes (Ranges in cm)	Conform to AHA bladder size recommendations • Infant (8-13) • Child (12-19) • Small Adult (17-25) • Adult (23-33) • Large Adult (31-40) • Thigh (38-50)	Conform to AHA bladder size recommendations • Infant (8-13) • Child (12-19) • Small Adult (17-25) • Adult (23-33) • Large Adult (31-40) • Thigh (38-50)
Repeated Inflations	10,000 inflations 3,000 hook and loop closures	10,000 inflations 3,000 hook and loop closures

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 3 2002

GE Medical Systems Information Technologies
c/o Mr. Jeff D. Rongero
Project Engineer
Underwriters Laboratories Inc.
12 Laboratory Drive, P.O. Box 13995
Research Triangle Park, NC 27709-3995

Re: K022482
Trade Name: Sensa-Cuff Blood Pressure Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II (two)
Product Code: DXQ
Dated: July 26, 2002
Received: July 29, 2002

Dear Mr. Rongero:

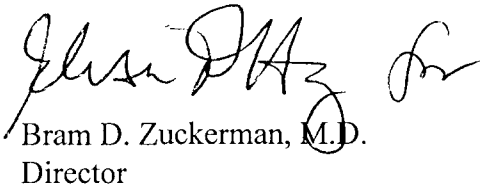
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

June 24, 2002 Page 1 of 1

510(K) Number (if known): K022482

Device Name: Sensa-Cuff Blood Pressure Cuff

Indications for Use:

The Sensa-Cuff Blood Pressure Cuff is an accessory used in conjunction with noninvasive blood measurement systems. The cuff is non-sterile and may be reused. It is available in pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.

(Please Do Not Write Below This Line-Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices
510(k) Number K022482

8/14/02

(Optional Format 1-2-96)